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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,046	10/30/2003	Michael E. Landry	5259-10801	1199
23492	7590	06/11/2007	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			CUMBERLEDGE, JERRY L	
			ART UNIT	PAPER NUMBER
			3733	
			NOTIFICATION DATE	DELIVERY MODE
			06/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/698,046

Applicant(s)

LANDRY ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,32-43,51,65,66 and 70 is/are pending in the application.
- 4a) Of the above claim(s) 13-20,65,66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,21,32-43 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Roger (US Pat. 6,592,587 B1).

Roger discloses a flexible (column 6, lines 15-16) member (Fig. 4, ref. 20) for a spinal stabilization system, comprising: a first section comprising a first stiffness (column 6, lines 15-16); a second section comprising a second stiffness (column 6, lines 15-16) and adapted for removable attachment to a head portion of a bone screw; and wherein the stiffness of the second section is greater than the stiffness of the first section. Since the flexible member can be made of two different materials (a polymeric material and another material), the wire will have at least two sections- a first section made of one material and a second section made of another material. Since the two different sections are made of two different materials that have different physical properties, the two sections will exhibit different stiffness. The section with the material

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that is stiffer can be considered the second section, and the section with the material that is less stiff can be considered the first section.

With regard to statements of intended use and other functional statements (e.g. ...adapted for removable attachment to a head portion of a bone screw...), they do not impose any structural limitations on the claims distinguishable over the device of Roger, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 21, 32-43 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benzel et al (US Pat. 5,713,900) in view of Roger (US Pat. 6,592,587 B1).

Benzel discloses a system for stabilizing a spine, comprising: a first threaded member (Fig. 1, ref. 92, top left screw) configured to couple to a first bone during use; a second threaded member (Fig. 1, ref. 92, bottom left screw) configured to couple to a second bone during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14), wherein the coupling mechanism is configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14), wherein the coupling mechanism is positionable using the first flexible member and the second flexible member during use, and wherein the coupling mechanism is configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14), wherein the coupling mechanism comprises: a first ring (Fig. 4, ref. 78) configured to engage a portion of the first threaded member during use; and a second ring (Fig. 4, ref. 78) configured to engage a portion of the second threaded member during use. The system further comprises a coupling mechanism, wherein the coupling mechanism comprises a ring (Fig. 4, ref. 78) configured to engage a portion of the first threaded member or the second threaded member during use. The system further comprises a coupling mechanism, wherein the coupling mechanism comprises: a first ring (Fig. 4, ref. 78) comprising protrusions (Fig. 4, ref. 84) (column 3, lines 49-52) configured to engage protrusions on a head of the first threaded member (Fig. 3, ref 42) during use; and a second ring (Fig. 4, ref. 78) comprising protrusions (Fig. 4, ref. 84) (column 3, lines 49-52) configured to engage protrusions on a head of the second threaded member during

use. The system further comprises a coupling mechanism, wherein the coupling mechanism comprises: a first connector (Fig. 1, ref. 14) configured to engage the first threaded member positioned in bone; a second connector (Fig. 1, ref. 12) configured to engage the second threaded member positioned in bone; and an elongated section (Fig. 1, ref. 10) configured to couple the first connector to the second connector.

Benzel further discloses a system for stabilizing a spine comprising: a first threaded member (Fig. 1, ref. 92, top left screw) comprising an inner conduit (Fig. 3, ref. 52) and configured to couple to a first vertebra during use; a second threaded member (Fig. 1, ref. 92, bottom left screw) configured to couple to a second vertebra during use; and a coupling mechanism (Fig. 1 ref. 10, 12 and 14) comprising: a first connector (Fig. 1, ref. 14) configured to engage a portion of the first threaded member during use; a second connector (Fig. 1, ref. 12) configured to engage a portion of the second threaded member during use; and an elongated member (Fig. 1, ref. 10) configured to couple to the first connector and the second connector such that the first vertebra is coupled to the second vertebra. At least one of the connectors comprises a curvate wall (Fig. 3, near ref. 38) to engage a portion of a ring during use. The inner conduit of the first threaded member comprises a threading (Fig. 3, ref. 52), and wherein the threading is configured to engage threading of the flexible member. The system further comprises a ring (Fig. 4, ref. 78) configured to couple at least one of the threaded members to at least one of the connectors during use; and wherein at least one of the connectors is configured to frictionally lock the ring. When the screw is fully engaged into the bone, the screw head will frictionally hold the ring in place.

Benzel further discloses a system for stabilizing a spine, comprising: a first threaded member (Fig. 1, ref. 92, top left screw) configured to couple to a first portion of bone during use; a second threaded member (Fig. 1, ref. 92, bottom left screw) configured to couple to a second portion of bone during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) positionable using the first flexible member and the second flexible member during use, and wherein the coupling mechanism is configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) comprising: a first ring (Fig. 4, ref. 78) configured to engage a portion of the first threaded member during use; and a second ring (Fig. 4, ref. 78) configured to engage a portion of the second threaded member during use. The system further comprises a coupling mechanism comprising: a first connector (Fig. 1, ref. 14) configured to engage the first threaded member positioned in bone; a second connector (Fig. 1, ref. 12) configured to engage the second threaded member positioned in bone; and an elongated section (Fig. 1, ref. 10) configured to couple the first connecting section to the second connecting section. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) comprising at least one connector (Fig. 1, ref. 14) configured to engage a threaded member during use. The first flexible member is positionable through the first threaded member opening in a coupling mechanism during use. The first flexible member is positionable through the first threaded member opening

in a coupling mechanism during use, and wherein the second flexible member is positionable through a second threaded member opening in the coupling mechanism during use.

Benzel further discloses a bone stabilization system, comprising: a threaded member (Fig. 1, ref. 92, top left screw) comprising one or more protrusions (Fig. 3, ref. 42) on a head of the threaded member; a ring (Fig. 4, ref. 78) configured to engage protrusions on the head of the threaded member during use; a coupling mechanism (Fig. 1 ref. 10, 12 and 14) configured to engage the threaded member during use comprising: an opening (Fig. 4, ref. 79) through a connector configured to engage the threaded member during use; and a locking mechanism (Fig. 3, ref. 60, the insert) configured to couple the threaded member to the ring during use; and wherein the system is configured such that interaction of protrusions on the head of the threaded member and the ring inhibits rotation of the threaded member in the bone during use. Benzel further discloses a ring (Fig. 4, ref. 78) configured to couple a threaded member to a coupling mechanism during use, comprising: a first surface configured to engage a wall of the coupling mechanism during use (the surface between the end of the ring and the beginning of the coupling mechanism); a second surface configured to engage a locking mechanism during use (sloped surface adjacent the surface of ref. 140); and a third surface comprising one or more teeth (surfaces near ref. 138) configured to engage a portion of the threaded member during use such that rotational movement of the threaded member in bone during use is inhibited.

Benzel does not disclose a first flexible member; a second flexible member; the first flexible member and the second flexible member are guides; one or more guiding mechanisms; a first flexible member; and a second flexible member; at least one of the flexible members comprising a cable; at least one of the flexible members comprising a variable thickness cable; at least one of the flexible members comprises a stopping mechanism.

Roger discloses a first flexible member (Fig 3b, ref. 21) adapted for removable attachment to the first threaded member to position one or more additional components proximate to the first threaded member during use; a second flexible member (Fig. 3a, ref. 21); the first flexible member and the second flexible member are guides (column 5, lines 37-40); one or more guiding mechanisms (Fig 3b, ref. 21); a first flexible member (Fig 3b, ref. 21); and a second flexible member (Fig. 3a, ref. 21); at least one of the flexible members comprises a cable (column 5, lines 44-45); and at least one of the flexible members comprises a variable thickness cable (Fig. 3b, ref. 21). Since the cable can be threaded, there will be a varying thickness along the cable. The cable will be thicker where there is threading and narrower where there is no threading. At least one of the flexible members comprises a stopping mechanism (Fig. 4, ref. 10). The flexible members (or guides) are used for guiding a securing member in the appropriate direction to achieve fixation of the objects to be fastened in a desired alignment (column 5, lines 37-40).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the flexible members (or guides) of Roger with the

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threaded member of Benzel, in order to guide a securing member in the appropriate direction to achieve fixation of the objects to be fastened in a desired alignment (column 5, lines 37-40).

Response to Arguments

Applicant's arguments filed 03/19/2007 have been fully considered but they are not persuasive.

In regard to Applicant's argument that Roger's disclosed use of a flexible member does not anticipate Applicant's use of a flexible member coupled to the head of a screw used in spinal stabilization, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In regard to Applicant's argument that there would be no motivation to combine the references the Examiner respectfully disagrees. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the flexible members (or guides) of Roger with the threaded member of Benzel, in order to guide a securing member in the appropriate direction to achieve fixation of the objects to be fastened in a desired alignment (Roger, column 5, lines 37-40).

In regard to Applicant's arguments directed to the positioning of the flexible member relative to the head portions of the threaded members, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus

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satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). The flexible members disclosed by Roger are capable of being coupled with the head portions of the threaded fasteners of Benzel.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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SUPERVISORY PATENT EXAMINER